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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,733	11/02/2001	Sunanda R. Kulkarni	MCP-291	3078
27777	7590	04/27/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/001,733		KULKARNI ET AL.	
	Examiner		Art Unit	
	David M. Naff		1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/03 & 2/5/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,13,17,22,23,28,32,37-43,45 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) 37-43,45 and 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 13, 17, 22, 23, 28 & 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment of 2/5/04 was filed after an amendment of 11/28/03 that was non-compliant, and amended claims 7, 22 and 23, and canceled claims 9-12, 14-16, 18-21, 24-27, 29-31, 33-36, 44 and 46. Claims 1-6
5 have been previously canceled. Arguments are in the amendment of 11/28/03.

Claims in the application are 7, 8, 13, 17, 22, 23, 28, 32, 37-43, 45 and 47-49.

Claims 37-43, 45 and 47-49 are withdrawn from further
10 consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 6 of 3/4/03.

Claims examined on the merits are 7, 8, 13, 17, 22, 23, 28 and
32.

15 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed 11/2/01 (preliminary amendment) is objected to under 35 U.S.C. 132 because it introduces new matter into the
20 disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the abstract adds new matter to specification by describing a tablet and composition not described in the specification. According to the
25 specification (page 3, lines 30-35), when only lactase and

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microcrystalline cellulose are present, a preblend rather than a tablet exists. Additionally, the preblend is not disclosed as containing the amount of lactase and microcrystalline cellulose in the abstract. These amounts are described for the tablet (page 4, line 5 18, and page 5, lines 4-5). The preblend composition is described at page 3, lines 31-36. The specification additionally fails to support any mixture of the members of the Markush group of lines 5-7 of the abstract resulting from the abstract reciting "and mixtures thereof" (line 7). When the members of the group are recited in the 10 specification (page 4, lines 6-13), forming a mixture of any of the members is not disclosed. It is suggested that a new abstract be submitted.

Applicant is required to cancel the new matter in the reply to this Office Action.

15 ***Claim Rejections - 35 USC § 112***

Claim 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had 20 possession of the claimed invention.

The specification fails to support a range of "about 0.25 to about 5%" by weight lubricant in line 2 of the claim. There is adequate support for only "about 0.25 to about 6% by weight" lubricant as in claim 17.

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Claims 7, 8, 13, 17, 22, 23, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cayle (3,718,739) in view of Schwartz et al (4,034,035) and Bowman (3,954,979).

The claims are drawn to a tablet or composition containing about
5 3000 to 9000 FCC lactase, about 25-70 weight percent microcrystalline cellulose, and a lubricant. Also present may be materials selected from a group of including fillers, lubricants and gums.

Cayle discloses making tablets containing lactase. A composition from which the tablet is made contains lactase mixed with conventional
10 solid fillers or carriers such as cornstarch, talc, calcium phosphate and calcium sulfate (paragraph bridging cols 3 and 4). In Example 6 (col 9, lines 10-20), tablets are disclosed containing lactase, cornstarch, magnesium stearate and gelatin.

Schwartz et al disclose preparing tablets (col 1, line 6 and col
15 2, line 17) containing a lubricant (col 2, line 41), a mixture of microcrystalline cellulose and modified cornstarch in a ratio of microcrystalline cellulose to cornstarch of about 1:3 to 3:1 (col 3, lines 5-10), and an enzyme (3, line 66).

Bowman discloses (col 3, lines 5-49) dehydrating an admixture of
20 yeast and vitamins under conditions that do not inactivate enzymes in the yeast, grinding the dehydrated product to produce a granular product, admixing the dried granular product with a diluent, and forming the resultant dry blend into tablets. The diluent can be selected from corn or potato starch, microcrystalline cellulose and
25 mixtures thereof, and is preferably a mixture of corn or potato starch

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and microcrystalline cellulose in a ratio of from 20:80 to 80:20 (col 4, lines 25-30).

It would be obvious to replace a portion of the cornstarch in the lactase-containing tablet of Cayle (Example 6) with microcrystalline cellulose as suggested by Schwartz et al and Bowman preferring a mixture of corn starch and microcrystalline cellulose when preparing tablets containing an enzyme or material containing an enzyme. Using ratios of microcrystalline cellulose to cornstarch in the ratio ranges of Schwartz et al and Bowman would have inherently resulted in an amount of microcrystalline cellulose within the range of about 25 to 70% by weight as claimed. Additionally, 1 gram of 50,000 LU lactase in Example 6 of Cayle would have inherently resulted in FCC lactase units in the range of about 3000 to 9000 as claimed. The magnesium stearate in Example 6 of Cayle is a lubricant, and the amount used is within the percent by weight range of claims 17 and 32. The members of the Markush group of claims 8 and 23 include cornstarch that would have been provided when using a mixture of cornstarch and microcrystalline cellulose as set forth above. Furthermore, Cayle discloses (paragraph bridging cols 3 and 4) other members in the group of the claims, and these are conventional solid fillers and carriers.

Response to Arguments

Eisenhardt et al is no longer applied in the rejection. Therefore, the argument that Eisenhardt et al is not a reference because of the exclusion of commonly assigned prior art under

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103/102(e) (1233 OG 54 (Apr. 11, 2000)) is moot. This argument is not applicable to the references presently applied.

Double Patenting

Claims 7, 8, 13, 17, 22, 23, 28 and 32 are rejected under the
5 judicially created doctrine of obviousness-type double patenting as
being unpatentable over claims 1-11 of U.S. Patent No. 6,365,208 B1 or
claims 1-8 of U.S. Patent No. 6,057,139 or claims 1-7 of U.S. Patent
No. 6,660,313 B1 in view of Schwartz et al and Bowman, and if
necessary in further view of Cayle.

10 The claims of the patents require formulations containing lactase
and microcrystalline cellulose.

It would have been obvious to provide the claimed formulations
of the patents in tablet form in view of Schwartz et al and Bowman
producing enzyme-containing tablets containing microcrystalline
15 cellulose, and if necessary in further view of Cayle producing a
tablet contain lactase.

Response to Arguments

Applicants state that the option of filing a terminal disclaimer
will be addressed when the claims are otherwise allowable.

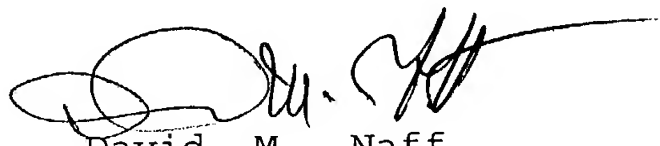
Conclusion

20 Any inquiry concerning this communication or earlier
communications from the examiner should be directed to David M. Naff
whose telephone number is 571-272-0920. The examiner can normally be
reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For
10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15

David M. Naff
Primary Examiner
Art Unit 1651

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DMN
4/23/04